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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,978	06/02/2000	Dr. Rudi Neirinckx	44334	5707

35928 7590 07/29/2004

GRAY CARY WARE FREDENRICH
1625 MASSACHUSETTS AVENUE, NW
SUITE 300
WASHINGTON, DC 20036-2247

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/584,978	NEIRINCKX, DR. RUDI	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13,15,16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13,15,16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. In view of the new grounds of rejection set forth below, the finality of the Office action mailed November 20, 2003 is withdrawn. The amendment after final rejection filed July 20, 2004 has been entered.

2. The claim amendments contained in the amendment filed July 20, 2004 are in improper format under 37 CFR 1.121(c) because they use status identifiers, i.e. "(Canceled without prejudice)" and "(Maintained)", which are not permitted under this section of the rule. In any response to this Office action, the claims need to be re-submitted in the correct format under 37 CFR 1.121.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of a combination of EGF and sulfadiazine, does not reasonably provide enablement for the administration of EGF not in combination with sulfadiazine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the

amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is the treatment of psoriasis in human patients with compositions comprising EGF, and optionally sulfadiazine or an anti-inflammatory. With respect to (2), the prior art of record does not teach using EGF to treat psoriasis in human patients. With respect to (3), the relative skill of those in the art is high. With respect to (4), according to the declaration by Inventor Neirinckx filed July 20, 2004, "there is no way to predict that a proposed treatment of psoriasis will be successful without an actual clinical trial". Therefore, it would not be possible to predict, in the absence of clinical trials, whether the treatment of psoriasis in humans outlined at page 2, third paragraph, would be successful if carried out with one less active ingredient. With respect to (5), the claims embrace administration of EGF without the administration of sulfadiazine. With respect to (6), Applicants' specification does not provide any direction or guidance as to how to administer EGF in the absence of sulfadiazine while still being able to treat psoriasis in humans. With respect to (7), there are no working examples in which psoriasis in humans is treated with EGF in the absence of sulfadiazine. The working example is limited to the use of combinations of EGF and sulfadiazine. With respect to (8), the quantity of experimentation necessary to practice the invention would be relatively great, requiring at least clinical trials in order to determine whether EGF in the absence of sulfadiazine can be used to treat psoriasis in humans. When the above factors are weighed, and especially in light of factor (4), it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

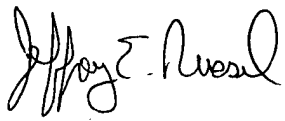
5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over the Nanney et al article (J. Invest. Dermatol., Vol. 98, pages 296-301) in view of the Phan et al article (Lancet, Vol. 348, page 547).. The Nanney et al article teaches treating psoriasis by topically administering sufficient EGF to downregulate EGF-R. In particular, the Nanney et al article teaches creams comprising 10 and 50 μg/ml EGF. Treatment is of active human psoriatic lesions grafted onto congenital athymic nude mice. The nude mouse model of psoriasis is described as being an "excellent biological tool to investigate the in vivo implications of an exogenous (paracrine) mode of cytokine delivery." See, e.g., the Abstract; page 29, column 1, second and third full paragraphs; and page 300, column 2, first full paragraph. The Nanney et al article does not teach using the EGF in combination with sulfadiazine. The Phan et al article teaches treating a severe case of psoriasis using a combination of active ingredients including silver sulfadiazine 1% cream. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use a combination of the EGF of the Nanney et al article with the silver sulfadiazine 1% cream of the Phan et al article because it is prima facie obvious to use combinations of ingredients each of which has been used individually for the same purpose (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), because the Phan et al article teaches that it is known to use combinations of active ingredients in order to treat severe cases of psoriasis, and because combining the silver sulfadiazine of the Phan et al article with the EGF of the Nanney et al article would permit the EGF of the Nanney et al article to be used for the treatment of severe cases of psoriasis. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal amounts and concentrations of the active agents in the drug combination, because amounts and concentrations

are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

6. With respect to the obviousness rejection of claims 15 and 16, note that in re-writing claim 15 in independent form, Applicant no longer requires the patient to be human. Accordingly, the declaration by Neirinckx filed July 20, 2004 does not demonstrate the unpredictability of the combination of references set forth in the rejection. This obviousness rejection would be withdrawn if claims 15 and 16 were to be amended to require that the patient be a human being.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel
July 27, 2004